Adopt Chapter 6, 17 Cal. Code of Regs. section 100600 to read:

Chapter 6 - Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees

§ 100600. Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees - Scope.

The regulations of this chapter apply to all California Institute for Regenerative Medicine ("CIRM") Grants awarded to Non-Profit and For-Profit Grantees on or after the effective date of these regulations. By accepting a CIRM Grant, the Grantee agrees to comply with these regulations. Any new or amended regulations subsequently adopted by the Independent Citizens Oversight Committee ("ICOC") will apply to Currently Active Grants on the start date of the next ~~non-competitive renewal~~Budget P~~p~~eriod after the effective date of the regulations, except amendments to Title 17, California Code of Regulations, sections 100606, 100607 and 100608, shall only apply to Grants awarded after adoption of the new or amended regulations. All revisions to CIRM regulations will be posted on the CIRM website at www.cirm.ca.gov, which shall serve as notice to the Grantee or Authorized Organization Official of such revisions.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100601 to read:

§ 100601. Intellectual Property Regulations - Definitions.

The following definitions apply to the regulations in this chapter:

(a) Authorized Organizational Official. The individual, named by the applicant organization, who is authorized to act for the applicant organization and to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to applications and awards.

~~The individual, named by the Grantee, who is authorized to execute agreements that legally bind the Grantee to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to Grant applications or Grant awards~~.

(b) Budget Period. The intervals of time (usually 12 months) into which a Project Period is divided for budgetary funding and reporting purposes.

(b) CIRM-Funded Invention. An Invention, whether patentable or not, which ~~(i)~~ arises from CIRM-Funded Research~~;~~ and ~~(ii) is~~ either (1) is conceived during the performance of a Currently Active Grant by a Grantee and/or its Collaborator(s) and~~/or~~ reduced to practice during the performance of a Currently Active Grant, or within ~~two years~~12 months of the close of the Grant, or (2) is reduced to practice during a Currently Active Grant~~.~~

(c) CIRM-Funded Research. All aspects of work conducted on a Currently Active Grant by a Grantee ~~[and/or]~~and its Collaborators(s) that is paid for, in whole or in part, with CIRM funds.

(d) CIRM-Funded Technology. Data, materials, research results or know-how whether patentable or not, that is generated or conceived in the performance of a Currently Active Grant and/or first reduced to practice during performance of a Currently Active Grant (or within ~~two~~

~~years~~12 months of the close of the Grant) and in all cases paid for in whole or in part with CIRM-funds.

(e) Collaborator. **[Option A: {**Any person or entity, other than a Grantee and Grantee Personnel, who conducts research and/or related work described in a Grant application~~.~~**} or B: {**Any person or entity other than a Grantee and Grantee Personnel who (i) receives directly or indirectly CIRM funding for work performed under a Grant, and (ii) who obtains ownership rights to a CIRM-Funded Invention or CIRM-Funded Technology.**}]**

(f) Currently Active Grant. A Grant: (i) that is still in the Project Period; ~~(ii) that is outside the Project Period but CIRM Grant funds are still being spent on the project;~~ or (~~i~~ii) for which the ~~repayment~~ return of unused or disallowed CIRM grant funds remains unsatisfied.

(g) Data. Recorded information, regardless of form or the media on which it may be recorded, including, but not limited to, recorded information of a scientific or technical nature, but not any of the following: financial, administrative, management data, other information incidental to contract administration, preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. "Data" excludes physical objects (e.g., laboratory samples).

(h) Drug. (1) An article recognized in the official United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States, or National Formulary, or any supplement to any of them; (2) an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or ~~other~~ animals; or, (3) an article intended for use as a component of any article specified in subdivision (1) or (2). This term includes therapeutic products such as blood, blood products, cells, and cell therapies.

(i) Exclusive License. A License Agreement that conveys to the licensee the exclusive

exercise of the right to make, use, sell, offer for sale and/or import in one or more fields of use or territories.

(j) Exclusive Licensee. Any individual or entity receiving all rights to make, use, sell, offer for sale and/or import in one or more fields of use or territories a CIRM-Funded Technology or a CIRM-Funded Invention, whether by assignment, license, or other mechanism.

(k) For-Profit Organization. A sole-proprietorship, partnership, limited liability company, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. ~~A legal entity that is organized for the profit or benefit of its shareholders or owners.~~

(l) Grant. ~~CIRM funding, other than a loan, in the form of a payment to conduct research and/or related work~~A funding mechanism, other than a loan, providing money and/or property to an eligible entity to assist the recipient in carrying out an approved project or activity.

(m) Grantee. The Non-Profit Organization or For-Profit Organization awarded a Grant by CIRM that is legally responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activity. The Grantee is the entire legal entity, including Affiliates, even if only a particular division is designated in the Notice of Grant Award ("NGA"). An entity is an Affiliate of a Grantee if both entities share substantial common direction or control (either directly or indirectly), or if either entity owns (directly or through one or more entities) at least a 25% capital or profits interest in the other. All University of California Grantee campuses shall be considered as separate and individual Grantees.

(n) Grantee Personnel. Grantee's Principal Investigator(s) and Grantee employees, students and contractors working under the direct or indirect supervision of the Principal Investigator under the Grant.

(o) Invention. A discovery that is conceived and/or reduced to practice, whether patentable or not.

(p) Inventor. A person who is an inventor under the patent law of the relevant governing jurisdiction.

(q) License Agreement. An agreement by which an owner of a CIRM-Funded Invention or CIRM-Funded Technology conveys the right to make, use, develop, sell, offer to sell, and/or import a CIRM-Funded Invention or CIRM-Funded Technology in exchange for consideration.

(r) Licensing Activities. Efforts of an owner or licensee of a CIRM-Funded Invention or CIRM-Funded Technology to negotiate, execute or enforce a License Agreement.

(s) Licensing Revenue. The consideration rendered to an owner or licensee of a CIRM-Funded Invention or CIRM-Funded Technology pursuant to a License Agreement. In the case of Non-Profit Grantees only, Licensing Revenue is calculated by subtracting amounts due to the Inventor pursuant to existing institutional policies from total consideration rendered. For all owners and licensees of a CIRM-Funded Invention or CIRM-Funded Technology, Licensing Revenue is calculated by subtracting a proportion of expenses reasonably incurred in prosecuting, defending and enforcing related patent rights equal to CIRM's percentage of support for development of such Invention and Technology total consideration rendered except to the extent that such expenses are recoverable from a third party as provided in Section 100405(d) or otherwise.

(t) Material Transfer Agreement ("MTA"). An agreement that governs the transfer of tangible research material between a Grantee and/or its Collaborator and an individual or entity ("Recipient") and defines the rights of the Grantee and the rights and limitations of the Recipient with respect to the materials and any derivatives.

(u) Net Commercial Revenue. Income from the sale or transfer, but not licensing or assignment, of a Drug or product(s) resulting in whole or in part from CIRM-Funded Research. Net Commercial Revenue excludes the following (as they pertain to the making, using or selling of products resulting from CIRM-Funded Research):

(1) import, export, excise and sales taxes, and customs duties;

(2) costs of insurance, packing, and transportation from the place of manufacture to the customer's premises;

(3) credit for returns, allowances or trades; and

(4) pre-commercial revenues received in connection with research and development and/or clinical activities.

(v) Non-Exclusive License. **Option A:** A License Agreement that transfers, or that conveys rights to more than one viable licensee, including co-exclusive and semi-exclusive arrangements. **Or Option b:** A License Agreement under which the rights transferred or conveyed to the licensee remain available to be licensed to other entities.

(w) Non-Exclusive Licensee. Any individual or entity that ~~shares with another viable individual or entity~~ obtains the right to make, use, sell, offer for sale and/or import in a specific field of use or territory, CIRM-Funded Technology or a CIRM-Funded Invention, through a Non-Exclusive License.

(x) Non-Profit Organization. A university or other institution of higher education or another organization of the type described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501 (c)(3)) and is exempt from taxation under 501 (a) of the Internal Revenue Code (26 U.S.C. 501 (a)) and California Revenue and Taxation Code section 23701d.~~;~~ ~~or any other non-profit scientific or educational organization qualified under a state non-profit~~

~~organization statute whose organizational charter provides that (A) the organization is not organized or operated for the private gain of any person, (B) no part of the organization's net income or assets shall inure to the benefit of any person, and (C) the organization's net assets upon dissolution shall be distributed to a non-profit fund, foundation or corporation which is organized and operated exclusively for charitable purposes.~~

(y) Notice of Grant Award ("NGA"). ~~The CIRM document that notifies the Grantee that an award has been made, contains or references all terms and conditions of the award, and documents the obligations of the Grantee~~The document that notifies the Grantee and others than an award has been made, contains or references all terms and conditions of the award as well as the Grantee's and Principal Investigator's agreement to those terms and conditions, and documents the commitment of CIRM funds.

(z) Principal Investigator. The Principal Investigator ("PI") is ~~one or more individuals designated by the Grantee to direct CIRM-Funded Research and who is accountable to the Grantee and to CIRM for the proper conduct of that research~~an individual designated by the Grantee to direct CIRM-Funded Research. He or she is responsible and accountable to the Grantee and CIRM for the proper conduct of the project or activity.

(aa) Project Period. The amount of time over which CIRM funds ~~research through a Granta~~ project or activity.

(bb) Public Funds. Funds belonging to the State of California or of any county, city, city and county, or other municipal corporation or subdivision thereof, or any public agency therein.

(cc) Publication-Related Biomedical Materials. Tangible research material of biomedical relevance first produced in the course of CIRM-Funded Research including but not limited to unique research resources (such as synthetic compounds, organisms, cell lines, viruses, cell

products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data), as described in a published scientific paper as provided by Title 17, California Code of Regulations, section 100603. Specific examples include specialized and/or genetically defined cells, including normal and diseased human cells, monoclonal antibodies, hybridoma cell lines, microbial cells and products, viruses and viral products, recombinant nucleic acid molecules, DNA probes, nucleic acid and protein sequences, certain types of animals including transgenic mice and other property such as computer programs. This term does not include tangible research material of biomedical relevance that is commercially available, as determined by CIRM pursuant to Title 17, California Code of Regulations section 100604, subdivision (e).

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100602 to read:

§ 100602. Invention and Licensing Reporting Requirements.

(a) Prior to an NGA and continuing through the end of the Currently Active Grant period, a Grantee must have written agreements with Grantee Personnel and Collaborators requiring prompt disclosure to the Grantee of any CIRM-Funded Invention or CIRM-Funded Technology.

(b) Within 60 calendar days after a CIRM-Funded Invention ~~or CIRM-Funded Technology~~ has been disclosed to a Grantee, the Grantee must notify CIRM of the CIRM-Funded Invention ~~or CIRM-Funded Technology~~ through the use of the CIRM Invention Disclosure Form, which will be received in confidence by CIRM. The Invention Disclosure Form shall identify the Grant under which the CIRM-Funded Invention ~~or CIRM-Funded Technology~~ was made, the Inventor(s) and the Principle Investigator. The Disclosure shall be sufficiently complete in technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, operation, and physical, chemical, biological or electrical characteristics of the CIRM-Funded Invention ~~or CIRM-Funded Technology~~. If the CIRM-Funded Invention ~~or CIRM-Funded Technology~~ has been submitted for publication or presentation, then the Disclosure shall identify the publication, the date of the abstract or manuscript or presentation, the submission date and if relevant any publication dates, including publication via the internet.

(c) A Grantee must submit annually to CIRM during, and for 15 years after, the Project Period of the Grant, an Invention Utilization Report that lists all CIRM-Funded Inventions, CIRM-Funded Technology (upon request by CIRM), patents and patent applications disclosing or claiming such CIRM-Funded Inventions or CIRM-Funded Technology and all Licensing

Activities, assignments, Exclusive Licenses, Non-Exclusive Licenses and Material Transfer Agreements ~~relating to~~conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology. Grantee shall have in place written agreements with its licensees and transferees described herein requiring such third parties to report to the Grantee information described below. The report by the Grantee to CIRM shall include~~, including but not limited to,~~ the following:

(1~~i~~) Grantees must report all patent applications filed disclosing and/or claiming any CIRM-Funded Inventions, including the countries in which application(s) were filed, application serial number(s), status and ~~-~~detailed description(s) of the CIRM-Funded Invention(s); and

(2~~ii~~) Grantees must report the issuance or abandonment of any patent applied for that discloses or claims a CIRM-Funded Invention, including the patent number and date of issuance or abandonment and the countries in which the applications have issued or have been abandoned; and

(3~~iii~~) Grantees must report the total funding from all sources that directly contributed to a CIRM-Funded Invention or CIRM-Funded Technology disclosed or claimed in the patent application, including each co-funder's identity, the dollar amounts each contributed and the dates of contribution. CIRM may audit all such co-funding reports; and

(4~~iv~~) A Grantee must report to CIRM the execution of all Exclusive License Agreements, Non-Exclusive License Agreements, Material Transfer Agreements or Collaborative Agreements ~~relating to~~conveying rights in CIRM-Funded Inventions or CIRM-Funded Technology; and

(5~~v~~) In the event that a CIRM- Funded Invention or CIRM-Funded Technology generates revenue or other consideration (whether from a License Agreement or otherwise), a Grantee

must report such revenue or consideration received during the preceding 12 month period or since the last report, whichever is longer.

(6) A Grantee must report the following key progress toward commercialization of a CIRM-Funded Invention or CIRM-Funded Technology:

(A) Initiation of clinical testing;

(B) Initiation of pivotal studies; and

(C) Application for marketing approval.

(d) These Invention Utilization Reports shall be marked "Confidential" in accordance with Health and Safety Code section 125290.30, subdivision (e)(2)(B).

(e) CIRM reserves the right to itself and its agents to conduct an audit of the Grantee and Collaborators to ensure compliance with these Regulations. Grantee must maintain and provide such documentation as is necessary to establish compliance. Further, Grantee must ensure that its Collaborators, Grantee Personnel and all Exclusive and Non-Exclusive Licensees maintain such documentation as is necessary to establish compliance. A Grantee shall have written agreements in place with third parties

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100603 to read:

§ 100603. Publication Requirements.

(a) Within 60 calendar days of the publication in a scientific journal, or the publication of an abstract in connection with a scientific meeting, of a CIRM-Funded Invention or CIRM-Funded Technology, the Grantee must submit to CIRM a Publication Disclosure Form containing ~~-~~a 500-word abstract written for the general public that highlights the findings of the publication, as well as a brief statement of the Principal Investigator's biographical credentials. The abstract and biographical statement will be ~~deposited into the~~ publicly-~~accessible~~ available by CIRM ~~electronic library repository, to be accessed via the CIRM website~~.

(b) One copy of each publication or abstract must accompany ~~the Invention Utilization Report submitted to CIRM pursuant to Title 17, California Code of Regulations, section 100602~~the Publication Disclosure Form. The form will identify the Grant Number, Grantee Institution, Principal Investigator and provide space for information identified in subdivision (a) of this regulation.

(c) A Grantee must ensure that the final abstract or manuscript includes the URL of a website where an MTA (or similar document) can be accessed to facilitate requests for Publication-related Biomedical Materials.

(d) Any written or oral publication reporting a CIRM-Funded Invention or CIRM-Funded Technology must acknowledge CIRM funding. An example of an acknowledgement is:

"This research was made possible by a grant from the California Institute for Regenerative Medicine (Grant Number _____). The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of CIRM or any other agency of the State of California."

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100604 to read:

§ 100604. Publication-Related Biomedical Materials Requirements.

(a) A Grantee shall share Publication-related Biomedical Material, for bona fide purposes of research in California. Such materials are to be shared without cost to the requestor or at the actual cost of providing the materials without an allocation of costs for overhead, research, discovery or other non-direct costs of providing the materials.

(b) A Grantee must share such materials within 60 calendar days of receipt of a written request, without bias as to the affiliation of the requestor, unless otherwise prohibited by law.

(c) CIRM may approve alternatives to this sharing requirement on a showing that:

(1) the number of sharing requests has become financially onerous for the Grantee;

(2) the material or its transfer could pose a public health risk; or

(3) the request is otherwise inappropriate, as determined by CIRM.

(d) In lieu of sharing as provided herein, a Grantee may provide requestors with the information necessary to reconstruct or obtain identical material.

(e) With prior approval from CIRM, a Grantee's obligations under this regulation may cease when the materials are made broadly commercially available.

(f) Prior to transferring any Publication-related Biomedical Material, a Grantee may require the requestor to execute an industry-standard or university-standard Material Transfer Agreement restricting the use and dissemination of such materials and its derivatives.

(g) A Grantee has no obligation under these regulations to share third party materials described in publications, patents, patent applications or presentations of CIRM-Funded Research or CIRM-Funded Technology or CIRM-Funded Inventions such as raw materials purchased by the Grantee to develop or synthesize the Publication-related Biomedical Material

or other materials covered by third party intellectual property rights, or if the Grantee is legally prohibited from doing so.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100605 to read:

§ 100605. Patents.

(a) Except as provided in Title 17, California Code of Regulations, section 100610, nothing in these Regulations grants CIRM an ownership interest in CIRM-Funded Research or CIRM-Funded Technology.

(b) Grantees may retain or transfer all or a portion of any of Grantee's right, title or interest to any CIRM-Funded Invention or CIRM-Funded Technology and to any patent or patent application relating thereto. Notwithstanding the foregoing, transfer of all or any portion of said right, title or interest must be made subject to provisions and obligations of these Regulations. Grantees must ensure that all arrangements entered with Grantee Personnel and Collaborators, and all transfers of all or any portion of right, title, or interest concerning CIRM-Funded Research, CIRM-Funded Inventions or CIRM-Funded Technology comply with these Regulations.

(c) Grantees shall bear the costs associated with any patent application disclosing or claiming any one or more CIRM-Funded Inventions, any patent itself, and all costs of pursuing, maintaining and protecting such applications patents.

(d) These Regulations shall not restrict the rights of Grantees to recover these costs through license fees or other consideration.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 1004606 to read:

§ 100606. Licensing and Assignment of CIRM-Funded Inventions and Technology.

(a) Subject to the provisions of Title 17, California Code of Regulations, section 100610, a Grantee shall make reasonable efforts to develop and commercialize CIRM-Funded Technology or CIRM-Funded Inventions.

(b) If a Grantee elects not to develop a CIRM-Funded Invention or CIRM-Funded Technology itself, then it shall make reasonable efforts to negotiate Non-Exclusive Licenses for third party development of such CIRM-Funded Inventions or CIRM-Funded Technology, unless (1) doing so would put the Grantee at a competitive disadvantage with a competitor, or (2) the Grantee through reasonable means shares or otherwise makes publicly available the CIRM-Funded Inventions or Technology ~~materials are already shared or otherwise publicly available.~~

(c) A Grantee may negotiate an Exclusive License for CIRM-Funded Invention or CIRM-Funded Technology if exclusivity is reasonably believed by the Grantee to be an economic incentive necessary to achieve commercial development and availability of the invention.

(1) A Grantee must document the development and commercialization capabilities of any intended exclusive licensee prior to entering into an Exclusive License.

(2) A Grantee must include in any Exclusive License terms addressing all reasonably anticipated therapeutic and diagnostic uses for the CIRM Funded Invention or CIRM-Funded Technology that the licensee is prepared to diligently develop and commercialize.

(3) A Grantee must include in any Exclusive License terms including:

(A) a commercial development plan to bring the invention to practical application, including milestones and benchmarks, so that the progress of development can be assessed and monitored;

(B) explicit remedies for failure to develop, including modification or termination of an Exclusive License in the event that a licensee is unable to fully develop the rights granted; and

(C) explicit grounds for modification or termination, such as failure to use commercially reasonable efforts to meet agreed-upon milestones or benchmarks, failure to negotiate in good faith alternative milestones or benchmarks, and failure to abide by subdivision (f) of this regulation.

(d) A Grantee may negotiate an Exclusive License for a CIRM- Funded Invention or CIRM-Funded Technology that is required for commercialization of a Drug, as defined in Title 17, California Code of Regulations, section 100601, subdivision (h), only if the licensee agrees to abide by the provisions of Title 17, California Code of Regulations, section 100607.

(e) Subject to the provisions of Title 17, California Code of Regulations, section 100410, a Grantee bears responsibility for Licensing Activities including identification of potential licensees, negotiation of License Agreements, and documentation of the progress and execution of development under a License Agreement for all CIRM-Funded Inventions or CIRM-Funded Technology. A Grantee must submit an annual Invention Utilization Report describing, among other things, these licensing and/or assignment activities as described in Title 17, California Code of Regulations, section 100602.

Optional Subdivision:

[(f) In licensing CIRM-Funded Inventions or CIRM-Funded Technology Exclusively or Non-Exclusively, Non-Profit Grantees shall retain the right to practice the use of its CIRM-Funded Inventions or CIRM-Funded Technology and to utilize the same ~~developed during the course of CIRM-Funded Research,~~ for its non-commercial purposes. A Non-Profit Grantee agrees to make its CIRM-Funded Inventions or CIRM-Funded Technology readily accessible on

reasonable terms, directly or through a licensee or licensees or other suitable means, to other Non-Profit Grantees for non-commercial purposes, upon request from a Non-Profit Grantee.]

(g) A Grantee must monitor and annually report to CIRM in its ~~Annual~~ Invention Utilization Report the performance of an Exclusive Licensee to ensure that said Licensee performs according to the milestones and benchmarks of the commercial development plan as described in section 100602, subdivision (c).

(h) A Grantee must take reasonable action to enforce the terms of an Exclusive License and must promptly report any material breach of an Exclusive License in writing to ~~the~~ CIRM ~~scientific program officer~~.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100607 to read:

§ 100607. Access Requirements for Products Developed by Grantees.

(a) A Grantee, a Collaborator or an Exclusive Licensee that is commercializing a Drug must submit a plan to afford uninsured Californians access to a Drug, as defined in Title 17, California Code of Regulations, section 100601, subdivision (e), which resulted in whole or in part from CIRM-Funded Research.

(b) A Grantee, a Collaborator or an Exclusive Licensee must submit this access plan to CIRM no fewer than 90 calendar days prior to the time the Drug is commercialized in California, unless CIRM agrees to shortened time.

(c) The access plan must be consistent with industry standards at the time of commercialization accounting for the size of the market for the Drug and the resources of the Grantee, the Collaborator or its Eexclusive Llicensee. Grantees, Collaborators and/or their Exclusive Licensees shall have the burden of establishing that the proposed access plan satisfies the requirements of this Section.

(d) The plan shall be subject to the approval of CIRM after a public hearing conducted by CIRM that provides for receipt of public comment. CIRM may adopt appropriate procedures to protect proprietary information submitted by Grantees, Collaborators and Exclusive Licensees in connection with said public hearing. Approval shall not be unreasonably withheld. Overall, CIRM shall not require that proposed Access plans exceed industry standards for such plans at the time of commercialization in California.

(e) The Grantee, Collaborator or an Exclusive Licensee is responsible only for providing the Drug itself, not any costs of administering the Drug or other attendant care.

(f) A Grantee, Collaborator, or an Exclusive Licensee must provide a Drug, the development of which was in whole or in part the result of CIRM-Funded Research, at a price as provided in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) (or a successor statewide prescription drug discount program) to eligible Californians under said program.

(g) A Grantee, Collaborator or its Exclusive Licensee must sell a Drug, the development of which is in whole or in part the result of CIRM-Funded Research, and which is purchased in California with Public Funds (as defined in Title 17, California Code of Regulations, section 100601, subdivision (q)) at any benchmark price described in the California Discount Prescription Drug Program or a successor statewide prescription drug discount program.

(h) This regulation is not intended, and this regulation shall not be construed, to preempt or prevent any other requirement under state or federal law or regulation, or agreement or contract, that would result in selling a Drug at a lower price than provided hereunder.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100608 to read:

§ 100608. Revenue Sharing.

(a) A Grantee, and Collaborator and Grantee Personnel must share with the State of California a fraction of Licensing Revenue the Grantee receives under a License Agreement for a CIRM-Funded Invention, or CIRM-Funded Technology, or results of CIRM-Funded Research, as follows:

(1) Subject to subdivision (a)(2) of this regulation, a Grantee must pay 25 percent of Licensing Revenue in excess of $500,000 to the State of California for deposit into the State's General Fund (such payments to be used by the State of California in a manner consistent with Title 35 United States Code, Section 202, subdivision (c)(7)). The threshold amount of $500,000 (in the aggregate) shall be adjusted annually by a multiple of a fraction, the denominator of which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the Bureau of Labor Statistics of the United States Department of Labor and published for the month of June 2008, and the numerator of which is such Index published for the month in which the Grantee accepts the Grant.

(2) If funding sources other than CIRM (including those of the Grantee) directly contributed to the development of said CIRM- Funded Invention or CIRM-Funded Technology, then the return to the State of California on Licensing Revenue in excess of the threshold amount described in subdivision (a)(1) of this regulation shall be proportionate to the support provided by CIRM, as follows: The amount of CIRM funding of the CIRM-Funded Invention or CIRM-Funded Technology shall be divided by the total of funding provided by all sources, and that fraction shall be multiplied by 25. That numeral is the percentage due to the State of California of Licensing Revenue.

(b) A Grantee and, Collaborator and Grantee Personnel must share with the State of California a fraction of any Net Commercial Revenue it receives from a self-commercialized product resulting from its CIRM-Funded Research (regardless of whether a CIRM- Funded Invention or CIRM-Funded Technology is involved) as follows:

(1) A Grantee must pay royalties to the State of California for deposit into the State's General Fund on Net Commercial Revenue exceeding the threshold amount described in subdivision (a)(1) of this regulation. Total payments under this subdivision (b)(1) shall equal and not exceed three times the total amount of the CIRM Grant or Grants that led to the Product. The rate of payback in the form of a royalty shall be at a rate of three (3) percent of the annual Net Commercial Revenue from the Product, unless the Product achieves blockbuster status, as provided in subdivisions (b)(2) and (b)(3) below.

(2) If Net Commercial Revenue from a self-commercialized product resulting from its CIRM-Funded Research exceeds the milestone of $250 million per year, and then if Net Commercial Revenue exceeds the milestone of $500 million per year from a self-commercialized product resulting from its CIRM-Funded Research, then upon the first occurrence of each of these milestones the Grantee will pay to the State of California a one-time blockbuster payment of three times the total amount of the Grant or Grants.

(3) In addition to any amounts due under any other provision of this regulation, where a CIRM-Funded Invention(s) or CIRM-Funded Technology is involved in the achievement of Net Commercial Revenue realized by a Grantee equivalent to or greater than $500 million in any year, and where a CIRM Grant or Grants amounting to more than $5 million (in the aggregate) were made in support of CIRM-Funded Research that contributed to the creation of Net Commercial Revenue, the Grantee will pay the State of California one percent annually of Net

Commercial Revenue in excess of $500 million for the life of any patent covering a CIRM-Funded Invention or CIRM-Funded Technology, or 20 years after the close of the Grant if the CIRM-Funded Invention or CIRM-Funded Technology is not patented.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100609 to read:

§ 100609. Press Release Requirements.

A Grantee or Collaborator must notify CIRM's communications officer at least one calendar day in advance of issuing any press release that refers to CIRM-Funded Research.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100610 to read:

§ 100610. March-In Rights.

(a) CIRM may request that a Grantee or its Exclusive Licensee enter into a nonexclusive, partially exclusive, or Exclusive License Agreement with respect to a CIRM-Funded Invention or CIRM-Funded Technology, in any field of use or territory with a responsible applicant or applicants, upon terms that are reasonable under the circumstances.

(b) If a Grantee or its Exclusive Licensee refuses CIRM's request to enter into a License Agreement to a CIRM-Funded Invention or CIRM-Funded Technology as provided by this regulation, CIRM shall have the right to enter into such a license with an applicant on behalf of the Grantee or its Eexclusive Llicensee (march-in) if :

(1) the Grantee or its Exclusive Licensee has not made reasonable efforts to achieve practical application of a CIRM- Funded Invention and/or CIRM- Funded Technology, as applicable;

(2) the Grantee or its Exclusive Licensee have failed to provide or comply with a plan for access to a Drug in accordance with Title 17, California Code of Regulations, section 100607;

(3) the Grantee or Exclusive Licensee has unreasonably failed to use a CIRM- Funded Invention or CIRM- Funded Technology to alleviate public health and safety needs that constitute a public health emergency as declared by the Governor.

(c) One consideration in taking the action described in subdivision (b) of this regulation will be whether doing so will impinge on the Grantee's academic freedoms.

(de) CIRM will promptly notify a Grantee or its Exclusive Licensee of any adverse determination under this provision and the basis therefore, as well as its intention to exercise march-in rights ("March-In Notice").

(ed) CIRM will not exercise its march-in rights if the Grantee or its Excusive Licensee promptly takes action to cure the deficiency and such deficiency is cured sooner than one year from the date of the March-In Notice (or longer period by mutual agreement). With respect to a deficiency described in subdivision (b)(3) of this regulation, however, CIRM may exercise such right at any time in the event of a public health or safety emergency declared by the Governor and where CIRM finds that exercise of march-in rights is likely to alleviate the circumstances or conditions that give rise to the emergency declaration.

(fe) Within thirty (30) days of the date CIRM issues a March-In Notice, the subject Grantee may appeal CIRM's decision to the ICOC by notifying the President of CIRM in writing of its intent to appeal CIRM's decision. Within sixty (60) days of the March –In Notice date, the subject Grantee must submit a written statement of the reasons for the appeal and any supporting materials it wishes to have considered by the ICOC. Absent extraordinary circumstances, the ICOC shall render a final determination on the appeal within one hundred twenty (120) days of the March-In Notice. In cases where an appeal is filed, CIRM shall not effect a march-in unless and until the ICOC renders a final determination on the appeal. The ICOC may reverse the decision of the CIRM to exercise march-in rights under this regulation for any reason.

(gf) Unless provided otherwise by CIRM, any applicant to receive a License or Assignment pursuant to this regulation will be bound by this Chapter as if it were an original Grantee recipient of the funding that resulted in the applicable CIRM-Funded Invention or CIRM-Funded Technology.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100611 to read:

§ 100611. Assurance of Third-Party Compliance.

Option A: Grantee shall take affirmative steps to document and ensure compliance with applicable CIRM regulations by Grantee Personnel, Collaborators, licensees and other transferees of right, title or interest any CIRM-Funded Invention or CIRM-Funded Technology, CIRM-Funded Research. Grantee agrees to provide documentation establishing compliance by third-parties at CIRM's request. In the event a Grantee fails to provide CIRM with adequate documentation to establish third-party compliance, CIRM may require Grantee to perform an audit of the third-parties and compel their compliance at the Grantee's expense.

Or

Option B: In the event that a Grantee or Collaborator is purchased or merges with a third party, the obligations of the Grantee and/or Collaborator will transfer to such third party as a successor.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Section 125290.30, Health and Safety Code.